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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,469	11/03/2001	David W. Buck	17810-510 NATL	3254

7590 11/30/2004

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EXAMINER	
HAYES, ROBERT CLINTON	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,469	BUCK ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *52-60 and 63-64* is/are allowed.

6)☒ Claim(s) *61,62 and 65-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. The amendment filed 9/07/04 has been entered. It is noted that no new IDS was submitted, in contrast to Applicants' assertions on page 8 of the response.

2. The rejection of claims 1-2, 5, 7-10, 13, 16, 20 & 25 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-7, 9, 8, 12 & 13 of prior U.S. Patent No. 6,468,794 B1 is withdrawn due to the cancellation of these claims and Applicants' arguments on page 9 of the response.

3. The rejection of claims 3, 4, 6, 11-12, 14-15, 17-19, 22, 24 & 26 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,468,794 B1 is withdrawn due to the cancellation of these claims and Applicants' arguments on page 9 of the response concerning the additional step of immuno-negative selection of CD45 & CD34 expressing cells.

4. The rejection of claims 1-20, 22 & 24-26 under 35 U.S.C. 112, second paragraph, as being indefinite for the recitation of what constitutes a "reagent" is withdrawn due to the cancellation of the claims.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Applicants' arguments filed 9/07/04 have been fully considered but they are not deemed to be persuasive.

7. Claims 52-60 & 63-64 are allowed.

8. Claims 66-72 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing a population of highly enriched human CNS stem cells using identifiable/deposited antibodies, does not reasonably provide enablement for methods of isolating highly enriched populations of human CNS stem cells using unknown or uncharacterized antibodies, or using unknown and undescribed "selecting" methodology. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons made of record for cancelled claims 1-20, 22, 24-26 in Paper No: 20040405, and as follows.

As previously made of record, the specification describes on pages 4-5 (i.e., as it also relates to the incorporation by reference of the Weiss patents) that only embryonic CNS brain regions and certain regions within the adult CNS (i.e., subventricular regions and dentate gyrus of the hippocampus) contain CNS neural stem cells, versus the invitation to discover other "neural or neural-derived" regions that do not reasonably contain neural stem cells, as

encompassed by new claims 66-70, and especially claim 68. For example, claims 66, 67, 69 & 70 recite "obtained/dissociated from neural tissue/a neural cell culture/an adherent monolayer culture", which do not reasonably contain neural stem cells after-the-fact, and therefore, are not commensurate in scope with the guidance provided within the instant specification, or that accepted within the state of the art at the time of filing Applicants' invention, as illustrated by the teachings of the referenced Weiss patent; thereby, requiring undue experimentation for one of skill within the art to know how to make the instant claimed method work, as currently recited.

Accordingly, the court in *Novo Nordisk v. Genentech*, 42 USPQ2d 1001 (Fed. Cir. (N.Y.), 1997), held that "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Second, as previously made of record, new claims 71 & 72 sets forth no structural characterization and little functional characteristics for determining when the skilled artisan is in possession of the required components necessary for practicing the instant invention, and in contrast, still encompass use of any biologically functional equivalent antibody, or use of other unknown "selecting" procedures/reagents not described within the instant specification. Therefore, the lack of guidance provided in the specification as to what minimal structural components are necessary for practicing the currently claimed invention, which includes undefined "selecting" steps/reagents for producing "human CNS stem cells", would prevent the skilled artisan from knowing how to make and use the instant invention without requiring undue experimentation to determine otherwise, for the reasons previously made of record; consistent with the teachings of Geysen et al previously made of record. Thus, these claims are not

commensurate in scope with that disclosed within the instant specification, and therefore are not enabled, for the reasons made of record.

Accordingly, the court held in *Ex parte Maizel* (27 USPQ2d 1662 at 1665), as it relates for the components required to practice the claimed methods, that:

> Appellants have not chosen to claim the DNA [product] by what it is but, rather, by what it does, i.e., encoding either a protein exhibiting certain characteristics, *or* a biologically functional equivalent thereof. Appellants' claims might be analogized to a single means claim of the type disparaged by the Court of Customs and Patent Appeals in *In re Hyatt,* 708F.2d 712, 218 USPQ 195 (Fed. Cir. 1983). The problem with the phrase "biologically functional equivalent thereof" is that it covers any conceivable means, i.e., cell or DNA, which achieves the stated biological result while the specification discloses, at most, only a specific DNA [product] segment known to the inventor. Clearly the disclosure is not commensurate in scope with the claims."

9. Claim 72 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons made of record for cancelled claim 19 in Paper No: 20040405, and as follows.

As previously made of record, in that 8G1 still appears to be antibody designation, versus a well-known antigen designation (i.e., CD24, instead; see page 9 of the specification), this claim is indefinite.

It is noted that Applicants did not address this particular rejection.

10. Claims 61-62, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

No proper antecedent basis exists for "**said** antibod**ies**", versus "monoclonal antibody" in base claims 52, 57, 58, 59 or 69. It is suggested that amending claims 61 & 62 to "wherein all of the antibodies" are fluorochrome conjugated" should obviate this rejection.

11. Claim 75 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons made of record for cancelled claim 26.

It remains unknown what the metes and bounds "**a** neural survival factor (NSF)" entail, when the claim is not reasonably directed to only that alternatively described on page 19 of the specification, where only the one specific NSF molecule available from Clonetics is described, versus generic neural survival factors, as encompassed by the current claim language.

It is suggested that amending claim 75 to "comprises [a] neural survival factor, [(]NSF[)]" should obviate this rejection.

12. Claims 73-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Steps (e) and (f) in claim 73 are inconsistent with steps (b) and (d), in that steps (e) and (f) recite "**or** CD45- or CD34-", in which the cells must be both AC133+ "and/or" 5E12+ "**and**" CD45- "and/or" CD34-; thereby, making the current claims ambiguous and indefinite.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert C. Hayes, Ph.D.
November 29, 2004

ROBERT C. HAYES, PH.D.
PATENT EXAMINER